

## REMARKS/ARGUMENTS

Claims 1, 3-4, 7-8, 10, 12, 14-29, and 36-39 are pending in this application. Claims 36-39 are amended.

Examiner has acknowledged that claims 1, 3-4, 8-12, 14-15, 17, 19, 21, 23, 25, and 27 are directed to allowable subject matter.

Claims 36-39 have been amended to correct a typographical error and indicate that the nucleotide sequence used to differentiate between *EpEP* and *epep* plants may be of at least 20 nucleotides in length. Support for this amendment can be found on page 33 line 10 to page 34 line 4, page 28 lines 1-5, as well as with reference to Figure 1, which indicates the primers used, Figure 5, which specifies the region for differentiation between *EpEp* and *epep* genotypes, and to SEQ ID NO:2.

### Rejection for Alleged New Matter

Claims 36-39 were rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. Applicant respectfully disagrees with Examiner's rejection of claims 36-39.

Claims 36-39 relate to methods that may be used to differentiate *EpEp* and *epep* genotypes that involve sequence comparisons between the genotypes. The use of sequences that may be used to distinguish *EpEp* and *epep* genotypes is described in several places within the specification, for example on page 10 line 16 to page 12 line 22 with reference to Figures 6-8, page 22 lines 4-9 and lines 15-20, Example 2, page 32 lines 3-20, and page 33 line 10 to page 34 line 4. On page 28 lines 1-5 there are provided examples of nucleotide sequences that may be used to distinguish between the *EpEp* and *epep* genotypes.

An example of a nucleotide sequence that resides within nucleotides 1524-1610 of SEQ

ID NO:2 (the 87 base pair region that differentiates the *EpEp* and *epep* genotypes) is “prx9+”, a 20 base pair sequence comprising the nucleotides ATGCATGCAGGTTTCAGT (see page 28 line 3). prx9+ is an example of a sequence that may be used to determine whether or not an 87 base pair sequence is present or absent within a sample. An example of alternate nucleotide sequence that may be used is “prx29” (CATAAACAAATACGTACGTGAT; page 28 line 5), a 21 base sequence, that spans the deletion (see page 11 line 14 to page 12 line 1, and Figure 8). prx29 may be used to determine the occurrence of the deletion present in *epep* genotypes as shown in Figure 8C since a smaller PCR product is produced using this nucleotide sequence when compared to a nucleotide sequence that does not reside within the deletion. The use of sequences prx9+, prx29 to identify *EpEp* and *epep* genotypes is exemplified in Figures 6-8, and described on page 22 lines 4-20, and page 33 line 10 to page 34 line 4.

It would be evident to one of skill in the art that other sequences within the 87 base pair region identified (nucleotides 1524-1610 of SEQ ID NO:2) can be used to differentiate the *EpEp* and *epep* genotypes using the methods disclosed. More particularly, a person of skill in the art would know that primers or nucleotide sequences used in the context of the claimed methods could be of varying lengths, and several different lengths of sequences are provided within the specification. For example, page 29 lines 15-16 (Example 1) refers to a 17-mer oligonucleotide primer. Other 20-mer primers are also used in the method of the present invention, for example, see prx2+, prx6-, prx10-, and prx12+ (page 28 lines 1-2 and 4-5). In addition, longer primers or nucleotide sequences are used or contemplated; for example prx29+ (page 28 line 5) is a 21-mer, and DNA molecules of at least 24 contiguous nucleotides (page 5 lines 13-15) are explicitly included in the present invention. Limitation of the claim to a specific primer as suggested by Examiner used would allow a competitor to circumvent these claims by using the teachings of the present application without requiring further experimentation.

Therefore, Applicant believes that amended claims 36-39 are amply supported by, and inherent in, the present specification. As such, Applicant requests withdrawal of the rejection to claims 36-39 under 35 U.S.C. 112, first paragraph.

### **Rejection for Alleged Lack of Enablement**

Claims 7, 16, 18, 20, 22, 24, 26, and 28-29 were rejected under 35 U.S.C. 112, first paragraph. Applicant respectfully traverses this rejection.

Examiner acknowledges that a number of regulatory sequences are disclosed, but states that the specific sequence disclosure that results in such activity is lacking. Examiner further alleges that undue experimentation would be required to practice such undisclosed sequences.

Claim 7 is directed to an isolated DNA molecule comprising a nucleotide sequence that hybridizes to nucleotides 1-1532 of SEQ ID NO:2 or a complement thereof under specific conditions, and that the DNA molecule exhibits transcriptional regulatory activity. Applicant notes that the claimed sequence is novel and unobvious in view of the prior art, the subject matter of the claim is support by at least one sequence within the scope of the claimed genus, and that there has been a reduction to practice of the disclosed species. As a result, this claim format is considered acceptable by the USPTO. In support of this argument, Applicant notes with reference to pages 36-37 of “Example 9: Hybridization”, of the “Synopsis of Application of Written Description Guidelines” (January 16, 2003; [www.uspto.gov/web/menu/written.pdf](http://www.uspto.gov/web/menu/written.pdf)), that for a sequence that is novel and unobvious in view of the prior art, where a single species is disclosed that is within the scope of the claimed genus, and where there is reduction to practice of the disclosed species, it is stated that:

“...a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are required to determine the applicant was in possession of the claimed invention.

**Conclusion:** The claimed invention is adequately described.”

Claims of a scope similar to that of claim 7, and with the same written description, are routinely allowed by the USPTO.

Applicant submits that a person of skill in the art would be readily able to identify a DNA molecule that hybridizes to nucleotides 1-1532 of SEQ ID NO:2 or its complement under the hybridization conditions defined in claim 7. Furthermore, as the sequence defined in claim 7 is free of any cited art, and as the sequence is defined in combination with the function of the sequence (transcriptional regulatory activity), Applicant submits that the scope of the claim is adequately described.

With respect to Examiner’s assertion of undue experimentation, Applicant submits that a skilled person would be amply familiar with methods of assessing the regulatory activity of a DNA molecule. For example, the specification refers to one non-limiting protocol for analysing the regulatory activity of a DNA molecule (see page 21 lines 8-12). Therefore, it would be a matter of routine experimentation for a skilled person to determine whether the DNA molecule that hybridizes to the nucleotides 1-1532 of SEQ ID NO:2 or its complement has transcriptional regulatory activity.

Applicant therefore submits that the subject matter of claim 7 and claims 16, 18, 20, 22, 24, 26, and 28-29 dependent thereon, are adequately defined by the present specification, and would not require any undue experimentation by a person of skill in the art.

Applicant requests the withdrawal of the rejection to claims 7, 16, 18, 20, 22, 24, 26, and 28-29 under 35 U.S.C. 112, first paragraph.

It is respectfully submitted that the above-identified application is now in a condition for allowance and favourable reconsideration and prompt allowance of these claims are respectfully requested. Applicants repeats his request for initiation of interference proceedings with U.S.

Patent No. 6,586,583. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact the applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

By 

Gary Tanigawa

Reg. No. 43180

901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100